

§ 58-3-221. Access to nonformulary and restricted access prescription drugs.

(a) If an insurer maintains one or more closed formularies for or restricts access to covered prescription drugs or devices, then the insurer shall do all of the following:

- (1) Develop the formulary or formularies and any restrictions on access to covered prescription drugs or devices in consultation with and with the approval of a pharmacy and therapeutics committee, which shall include participating physicians who are licensed to practice medicine in this State.
- (2) Make available to participating providers, pharmacists, and enrollees the complete drugs or devices formulary or formularies maintained by the insurer including a list of the devices and prescription drugs on the formulary by major therapeutic category that specifies whether a particular drug or device is preferred over other drugs or devices.
- (3) Establish and maintain an expeditious process or procedure that allows an enrollee or the enrollee's physician acting on behalf of the enrollee to obtain, without penalty or additional cost-sharing beyond that provided for in the health benefit plan, coverage for a specific nonformulary drug or device determined to be medically necessary and appropriate by the enrollee's participating physician without prior approval from the insurer, after the enrollee's participating physician notifies the insurer that:
 - a. Either (i) the formulary alternatives have been ineffective in the treatment of the enrollee's disease or condition, or (ii) the formulary alternatives cause or are reasonably expected by the physician to cause a harmful or adverse clinical reaction in the enrollee; and
 - b. Either (i) the drug is prescribed in accordance with any applicable clinical protocol of the insurer for the prescribing of the drug, or (ii) the drug has been approved as an exception to the clinical protocol pursuant to the insurer's exception procedure.
- (4) Provide coverage for a restricted access drug or device to an enrollee without requiring prior approval or use of a nonrestricted formulary drug if an enrollee's physician certifies in writing that the enrollee has previously used an alternative nonrestricted access drug or device and the alternative drug or device has been detrimental to the enrollee's health or has been ineffective in treating the same condition and, in the opinion of the prescribing physician, is likely to be detrimental to the enrollee's health or ineffective in treating the condition again.

(b) An insurer may not void a contract or refuse to renew a contract between the insurer and a prescribing provider because the prescribing provider has prescribed a medically necessary and appropriate nonformulary or restricted access drug or device as provided in this section.

(c) As used in this section:

- (1) "Closed formulary" means a list of prescription drugs and devices reimbursed by the insurer that excludes coverage for drugs and devices not listed.
- (1a) "Health benefit plan" has definition provided in G.S. 58-3-167.
- (2) "Insurer" has the meaning provided in G.S. 58-3-167.
- (3) "Restricted access drug or device" means those covered prescription drugs or devices for which reimbursement by the insurer is conditioned on the insurer's prior approval to prescribe the drug or device or on the provider

prescribing one or more alternative drugs or devices before prescribing the drug or device in question.

(d) Nothing in this section requires an insurer to pay for drugs or devices or classes of drugs or devices related to a benefit that is specifically excluded from coverage by the insurer. (1999-178, s. 1; 1999-294, s. 14(a), (b); 2001-446, s. 1.5.)